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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,584	06/19/2003	Robert W. Blakesley	55670DIV(45858)	5497

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EXAMINER	
BABIC, CHRISTOPHER M	
ART UNIT	PAPER NUMBER
1637	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/600,584	BLAKESLEY ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER M. BABIC	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *October 6, 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26,27,33-37 and 39-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26,27,33-37 and 39-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claim(s) 26, 27, 33-37, and 39-48 are pending and under examination. The following Office Action is in response to Applicant's communication dated October 6, 2009.

Claim Rejections - 35 USC § 103 - Maintained

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 26, 27, 33-37, and 39-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogers et al. ("Bacterial typing: storing and processing of stabilized reference bacteria for polymerase chain reaction without preparing DNA--an example of an automatable procedure" Anal Biochem. 1997 May 1;247(2):223-7) in view of Burgoyne (U.S. 5,496,562), and in view of Kahn et al. (Plasmid cloning vehicles derived from plasmids ColE1, F, R6K, and RK2" Methods Enzymol. 1979;68:268-80).

The claims are drawn to a method of isolation of vectors from host cells by contacting the host cells with a solid medium. In some embodiments the solid medium protects the vector from degradation, is made of cellulose or a micromesh plastic, the host cells are in solution, and the solid medium comprises urate salt, a chelating agent, and an anionic detergent.

Rogers et al. shows in the abstract and throughout recovery of DNA from bacterial liquid cultures by application of the bacterial culture to FTA® blood storage medium. Figures 1 and 2 show positive results of PCR assay of bacterial DNA from FTA® media to which bacterial cultures were applied. Rogers et al. shows that the DNA is stable for at least 1.6 years after application to the FTA® media on page 226. Rogers et al. does not show use of bacteria comprising vectors, media comprising micromesh plastic, and Rogers et al. does not detail the composition of the chemicals in the FTA media. Rogers et al. states on page 223 that FTA® medium is described in Burgoyne (U.S. Patent No. 5,496,562).

Burgoyne shows the components of a solid medium for preserving DNA from blood cells in columns 2-4, including use of a solid support such as cellulose or a micromesh of a synthetic plastic (column 2, lines 21-23), urate, an anionic detergent, and a chelating agent (column 2, lines 54-64 and column 3, lines 18-26). Burgoyne shows the application and storage of isolated plasmids on the solid medium in Example 2, columns 4-6. Burgoyne discloses application of plasmid pUC19 and recovery of approximately 100% of the applied plasmid from the solid matrix in column 6. Burgoyne claims a method of application of generic DNA and recovery of the applied DNA from a solid matrix in at least claim 6.

Kahn et al. reviews plasmid cloning vectors, and shows that such vectors are replicated in bacteria in the abstract and throughout. Kahn et al. shows on page 268 that plasmid vectors are useful for cloning and maintenance of foreign DNA.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Rogers et al. by use of bacteria comprising vectors because Burgoyne shows that the solid media used by Rogers et al. can be used for long term storage and recovery of plasmids, and Kahn et al. shows that bacterial plasmid vectors are useful for cloning and maintenance of foreign DNA.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

The declaration under 37 CFR 1.132 filed October 6, 2009 is insufficient to overcome the rejection of claims 26, 27, 33-37, and 39-48 based upon the combination of Rogers, Burgoyne, and Kahn under 35 USC 103(a) as set forth in the last Office action because: the showing is not fully commensurate in scope with the claimed invention.

As understood by the examiner, Applicant is attempting to rebut the instant case of obviousness by asserting that a person of ordinary skill in the art would not have had a reasonable expectation that plasmid DNA could have been isolated from the claimed solid support while in the presence of the host genome and other associated cellular material, due to the limited number of available sites on the support, i.e. one would not have expected that the very limited number of plasmids could bind to the solid support in the presence of the vast bacterial genomic and cellular protein material (see King Declaration pg. number 7-10, for example). This argument is not persuasive because: 1) Applicant has based the argument solely in the context of low copy plasmids, i.e. section 7-10 of the King Declaration explicitly reference low copy plasmids. Such an argument is not fully commensurate in scope with the claimed invention, which encompass all plasmids (e.g. high copy, adjustable, for example) as well as host vectors (bacteria, yeast, etc.); and 2) with specific regard to claims 26, 27, 33-37, and 39-41, the claimed invention does not expressly require that the plasmid DNA actually come in contact with the solid support. As understood by the examiner, when a host cell, either by liquid or colony, is placed upon the solid support, all of the cell contents including the plasmid DNA remain with cell lysate on the solid support through storage

until processing; notably any process that will potentially remove any unbound plasmid DNA, e.g. washes. As claimed, the plasmid DNA remains with the cell lysate immediately prior to isolation. Thus, the arguments presented by Applicant are relevant only in an instance where the claims require either the plasmid DNA to actually contact the solid support (e.g. claims 43-48) or a method step that would potentially remove plasmid DNA from the whole cell lysate prior isolation from the solid support. Furthermore, the term "isolation" is not defined by the claim or specification to require any specific method step.

Applicant is reminded that a showing of unexpected results must be commensurate in scope with the claimed invention. Furthermore, "The nonobviousness of a broader claimed range can be supported by evidence based on unexpected results from testing a narrower range if one of ordinary skill in the art would be able to determine a trend in the exemplified data which would allow the artisan to reasonably extend the probative value thereof. *In re Kollman*, 595 F.2d 48, 201 USPQ 193 (CCPA 1979)." (see MPEP 716.02(d)) Thus, given that claimed invention encompasses a genus of host cells as well as plasmids, evidence that the specific example provided by Applicant (see King Declaration, section 9 calculation) would indicate a trend to one of ordinary skill in the art must be provided. For example, if Applicant provides an example calculation with a host cell comprising a comparably smaller amount of genomic DNA within the genus of host cells, in combination with a vector of a comparably higher copy with the genus of plasmids, then the result-based conclusions of Applicant would clearly show a trend over the entire genus of the claimed invention.

Thus, the rejection is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 814-880-9945. The examiner can normally be reached on Monday-Friday 10:00AM to 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher M. Babic/
Primary Examiner
Art Unit 1637
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